510(k) SUMMARY

(Submitted As Required per 21 CFR 807.92(c))

GENERAL INFORMATION:

510k Owner's Name	Bovie Medical Corporation
Establishment Registration Number:	3007593903
Address	5115 Ulmerton Road Clearwater, Florida 33760-4004 United States of America
Telephone Number: **FAX Number:**	(727) 384-2323 (727) 322-4465
Contact Person:	Richard A. Kozloff Vice-President; Quality Assurance/Regulatory Affairs
Date Prepared:	December 27, 2013

DEVICE IDENTIFICATION:

Trade Name/Model Number:	Bovie® IDS-310 High Frequency Electrosurgical Generator
Common Name:	Electrosurgical Generator (ESU)
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification:	21CFR 878.4400; Class II; Product Code GEI
Legally Marketed Predicate Device(s):	510(k) Number: K022856 Primary Predicate Device Name: Bovie IDS-300 High Frequency Electrosurgical Generator Manufacturer: Bovie Medical Corporation 510(k) Number: K083452 Secondary Predicate Name: ERBE VIO ESU (Model VIO 300D) Manufacturer: ERBE USA, INC.

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Device Description:

The IDS-310 Electrosurgical Generator is an electrosurgical device that utilizes High Frequency electrical current, via an assortment of surgical devices to cut and coagulate different kinds of tissue.

The IDS-310 Generator is a high frequency isolated generator featuring cutting up to 300 watts, 4 blend modes, 3 coagulation modes and 4 bipolar modes with an Auto Bipolar option. There is a characteristic electrical wave form associated with each mode. The electrical properties of the waveform (frequency and duration) produce the clinical effect (i.e. cut, coagulation). The shape and duration of waveforms are comparable between the generator and predicate devices. The generator offers 2 monopolar handpiece outputs, monopolar foot controlled output, bipolar handpiece output, and bipolar foot controlled output. The generator has a return electrode contact and quality monitoring system (NEM) to reduce the risk of patient burns at the return electrode site. The pad-sensing feature allows the user to use either a split or solid return electrode.

The generator is designed to comply with applicable Medical Electrical Equipment safety standards, including electromagnetic compatibility and other safety standards. It is also designed to meet the requirements of the European RoHS directive.

The device consists of a generator, power cord, and a User's Guide. The main device components are a front panel containing the power button, wattage selection buttons, LED numeric displays, alarm and return electrode indicator lights, and connector ports for accessories, a back panel consisting of footswitch ports, volume controls, a power cord outlet, and fuse, and internal components (printed circuit boards, speakers, cabling).

Bench testing was performed to demonstrate that the generator met design specifications and to establish substantial equivalence with predicate devices. Device testing and evaluation demonstrated compliance with the following:

IEC 60601-1: 2005
Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2: 2007
Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

IEC 60601-2-2: 2007
Medical Electrical Equipment - Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

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Substantial Equivalence:

Characteristic	Bovie® IDS-310 (This Submission)	Bovie IDS-300 High Frequency Electrosurgical Generator (K022856) Primary Predicate	ERBE ESU VIO300D (K083452) Secondary Predicate
Regulation and Product Code	21 CFR 878.4400 / GEI	Same	Same
Intended Use	Is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue	Same	Is intended to deliver high frequency (HF) electrical current for the cutting and/or coagulation of tissue.
Energy Type	High Frequency (RF)	High Frequency (RF)	High Frequency (RF)
Output	Monopolar and Bipolar	Monopolar and Bipolar	Monopolar and Bipolar

Similarities

Each device Uses high frequency RF current to deliver a desired clinical effect.

Each device offers monopolar and bipolar output modes.

The Cut I/II, Blend, Pinpoint Coagulation, and Spray Coagulation modes of the IDS-310 and IDS-300 predicate devices have the same waveform and maximum output power. The Bovie Bipolar mode of the IDS-310 has a similar waveform and the same output power as the VIO 300D BiClamp mode. Other IDS-310 Bipolar modes are similar to VIO 300D Bipolar modes but have lower output power.

Differences

The IDS-310 was designed compliant with both IEC 60601-1 Third Edition and the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive.

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Conclusions

The Bovie IDS-310 High Frequency Electrosurgical Generator has the same intended use, operating procedures, principles of operation, and utilizes the same technology as the predicate devices. The Bovie IDS-310 does not raise additional issues of safety or efficacy compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 17, 2014

Bovie Medical Corporated
Mr. Richard A. Kozloff
Vice President, Quality Assurance/Regulatory Affairs
5115 Ulmerton Road
Clearwater, Florida 33760

Re: K134054
Trade/Device Name: Bowie® IDS-310 High Frequency Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 27, 2014
Received: December 31, 2014

Dear Mr. Kozloff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K134054

Device Name: Bovie IDS-310 High Frequency Electrosurgical Generator

Indications for Use:

The IDS-310 High Frequency Electrosurgical Generator is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue.

Prescription Use ✓ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A
Date: 2014.03.14 15:51:14 -04'00'

FDA

for BSA

(Division Sign-Off)
Division of Surgical Devices
510(K) Number: K134054